FOSTER

Dear Valued Customer,

The biocompatibility of the ingredients used to formulate the Foster HLS™ additive package was tested in a hard (72D) and soft (25D) polyether-amide elastomer by a third party testing service (Nelson Laboratories) under ISO 10993 conditions. A summary of the tests and results are below:

"For safety evaluation of a biomaterial sample, rabbits were injected intracutaneously (Dose = 0.2 mL x 5 sites) with extracts of the test article and associated vehicle controls. Injection sites were examined and scored at 24, 48, and 72 hours after treatment for signs of skin reactions. The vehicles used were 0.9% normal saline, cottonseed oil, polyethylene glycol 400, and 5% ethanol in normal saline.

No apparent irritation was observed in associated with the 0.9% normal saline, cottonseed oil, PEG, or 5% ethanol in normal saline test article extract. Under the test conditions of this protocol, the difference in test articles scores was **less than 1.0**, indicating that **the requirements of the USP Intracutaneous test have been met by the test article.**

For safety evaluation of the test article, mice were injected systemically with extracts of the test article in standard solutions (normal saline, cottonseed oil, polyethylene glycol 400, and 5% ethanol in saline). The animals were observed for signs of toxicity immediately after injection and at 4, 24, 48, and 72 hours post-injection.

The vehicle control treated animals had no signs of toxicity at any of the observation periods and no animals lost weight in excess of 2 grams, indicating a valid test. None of the test article extract treated animals were observed with clinical signs consistent with toxicity at any of the observation periods. These findings indicate that **the requirements of the USP Acute Systemic Injection Test have been met by the test article.**

For safety evaluation of a test article, sections of the test article and negative control were implanted surgically in the paravertebral muscles of rabbits. After a one week exposure period, the animals were sacrificed and the paravertebral muscles removed. The implantation sites were examined macroscopically and scored for encapsulation.

The difference between the average encapsulation score for the test article implants and the negative control implants was 0 for animal #16921 and 0 for animal #16922. The overall score difference for all implantation sites was also 0. Based on these findings **the test article met the requirements of the USP Intramuscular Implant test.**"

The test results are specific to the samples prepared. Any further extrapolation of the results would be the responsibility of the user of the compound(s) containing the above mentioned additive package.

If you have any questions or require any additional information please do not hesitate to contact the undersigned.

Respectfully Submitted,

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Regulatory Manager

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